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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,771	03/19/2002	Kaneyoshi Kato	2648 US0P	2340

23115 7590 10/03/2003

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
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LINCOLNSHIRE, IL 60069

EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/03/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/088,771

Applicant(s)

KATO ET AL.

Examiner

Hong Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2, 4-12, 14-16, 17-20, 22-23, 25-26, 34, 36, and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-2, 4-12, 14-16, 17-20, 22-23, 25-26, 34, 36, 39-45 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ aryl, X is CONR^{8c}, Ar' is the first formula in claim 18, R1 and R2, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group II, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 28, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ aryl, X is CONR^{8c}, Ar' is the second formula in claim 18, R1 and R2, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group III, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, and 34, drawn to the compounds of formula I wherein Ar¹ aryl, X is CONR^{8c}, Ar' is the third formula in claim 18, R1 and R2, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group IV, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, and 34, drawn to the compounds of formula I wherein Ar¹ aryl, X is CONR^{8c}, Ar' is the fourth formula in claim 18, R1 and R2, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

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Group V, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, and 34, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the fifth formula in claim 18, R1 and R2, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group VI, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the first formula in claim 18, R1 and R2, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group VII, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 28, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the second formula in claim 18, R1 and R2, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group VIII, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the third formula in claim 18, R1 and R2, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group IX, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the fourth formula in claim 18, R1 and R2, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group X, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the fifth formula in claim

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18, R1 and R2, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group XI, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ aryl, X is CONR^{8c}, Ar' is the first formula in claim 18, R1 and R2 form a ring, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group XII, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 28, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ aryl, X is CONR^{8c}, Ar' is the second formula in claim 18, R1 and R2 form a ring, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group XIII, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ aryl, X is CONR^{8c}, Ar' is the third formula in claim 18, R1 and R2 form a ring, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group XIV, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ aryl, X is CONR^{8c}, Ar' is the fourth formula in claim 18, R1 and R2 form a ring, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group XV, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the fifth formula in claim 18, R1 and R2 form a ring, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

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Group XVI, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, 40-45, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the first formula in claim 18, R1 and R2 form a ring, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group XVII, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 28, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the second formula in claim 18, R1 and R2 form a ring, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group XVIII, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the third formula in claim 18, R1 and R2 form a ring, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group XIX, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the fourth formula in claim 18, R1 and R2 form a ring, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group XX, claim(s) 1-2, 4-12, 14-16, 18-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds of formula I wherein Ar¹ heteroaryl, X is CONR^{8c}, Ar' is the fifth formula in claim 18, R1 and R2 form a ring, Y and R2 do not form a ring, compositions and a method of use of the compounds selected from claims 35, 36, and 39.

Group XXI, 1-2, 4-12, 14-16, 17-20, 22-23, 25-26, 34, and 40-45, drawn to the compounds, composition, and methods of use not included in Groups I-XX.

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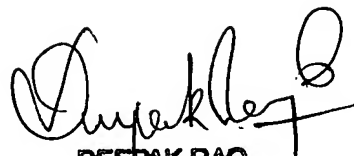
2. Group XXII, claim(s) 35, 36, and 39, drawn to a method of treatment not included in Groups I-XX.
3. The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: there are prior art for each of the groups. This means that a technical feature which already forms part of the state of the art cannot, by definition, make a contribution over the prior art and does not, therefore, qualify as an unifying element in the sense of Rule 13.1 PCT. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Tentative election of a single species and one utility with the elected group is further required.

1. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
2. Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for official business is (703) 308-4556. Any inquiry of a general nature or relating to the

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status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.



DEEPAK RAO
PRIMARY EXAMINER

hl
September 26, 2003

Mukund Shah
Supervisory Patent Examiner
Art Unit 1624